The Pudenz Flushing Valve, designed for placement in a formal burr hole, is a spherically shaped, silicone elastomer device used for the treatment of hydrocephalic patients when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. The valve incorporates an internal low, medium, or high pressure diaphragm for proximal control of CSF flow. The device also provides one-way flow control. The valve contains no metal parts to interfere with imaging technology. Due to internal reservoir capacity, no separate reservoir is usually required. Two models of the Pudenz Flushing Valve are available: Standard and Anti-Siphon. Both models incorporate integral straight connectors to simplify implantation and to eliminate two suture ties.

The Standard Model
The Standard Model Pudenz Flushing Valve is available in two sizes, one designed to fit a 12mm, the other a 16mm burr hole. A silicone elastomer diaphragm within the valve reservoir is designed to provide low, medium, or high shunt pressure control (depending on which pressure-range valve is selected) and to prevent the backward flow of CSF into the ventricles of the brain.

Three valve flow/pressure ranges are available to provide the surgeon a choice in meeting individual patient needs. Each valve is tested at the time of manufacture for conformance with labeled flow/pressure performance characteristics. The pressure ranges are identified by a tantalum-impregnated silicone elastomer dot code on the valve dome.

Valve performance characteristics are reported in accordance with a shunt valve test method contained in the American Society for Testing and Materials F647-86, "Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application." However, due to characteristics of silicone materials, some variation pressure performance may occur.

For a description of the pre-implant check for valve patency and valve-diaphragm performance, please refer to Instructions For Use.

Recommendations For Use of Low Pressure Distal Catheter
In order to allow the valve diaphragm to control shunt pressure, Integra NeuroSciences recommends the use of a low pressure distal catheter (closing pressure 54mm H2O or less) with the Pudenz Flushing Valve. (See Instructions For Use.)

The Pudenz Flushing Valve dome may be penetrated by a 25-gauge or smaller needle. Such penetration permits removal of CSF samples, as well as the injection of fluid materials in the distal direction. The flange overlying the skull contains sutural indentations to facilitate securing the device to the peristome.

Anti-Siphon Model
This model possesses all the characteristics of the standard model and includes the addition of an integral Anti-Siphon Device. This device, located distally (downstream) to the flushing valve, is designed to help prevent the excessive drainage of cerebrospinal fluid which would otherwise be caused by the siphoning effect created by the elevation of the ventricular catheter with respect to the distal catheter (i.e., when the patient sits, stands or is held erect). This siphoning effect is minimized by the anti-siphon device, which closes under a negative pressure, yet will reopen to allow the flow of CSF to resume before intraventricular pressure becomes excessive. The Anti-Siphon Device is designed to restrict flow when the shunt system is under substantial negative hydrostatic pressure. It is not designed to compensate for lowered intracranial pressure brought on by other than large negative hydrostatic pressure changes.

Indications
The Pudenz Flushing Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum.
Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Contraindications
Ventriculostial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

The ventriculostial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

Instructions For Use

Valve Patency and Closing Pressure Test

1. Connect a length of sterile tubing to the proximal tube or integral connector and elevate the tubing above the valve. No tubing should be connected to the distal integral tube, or connector.

2. Orient the valve such that the distal tube or integral connector is touching the test table.

3. Using a syringe, gently flush the valve and fill the tube to approximately 25 cm. The amount of pressure created by syringe flushing can temporarily deform the silicone elastomer valve, which will cause abnormally low pressure test results. Use sterile deaerated water to help eliminate air bubbles in tubing and valve. After flow through tubing and valve have been established, examine tubing and valve to insure bubbles have been eliminated.

4. When the water level falls within the intended pressure range (low—5 to 50 mm H2O; medium—51 to 110 mm H2O; or high—111 to 180 mm H2O) a noticeable slowing of flow should occur.

5. The valve closing pressure should be checked when the water level is at the lower limit of the range. The discharge from the valve outlet tube or connector should be less than or equal to 0.08 ml/min. when measured at the lower limit of the pressure range. The pressure is that recorded by measuring the distance from the base of the valve to the top of the water column in the proximal integral connector tube extension. Due to characteristics of silicone materials, some variation in pressure performance may occur.

The introduction of a shunting system, including placement of the flushing valve may be accomplished through a variety of surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient.

Injection

To inject fluids into the distal catheter, inject with a 25-gauge or smaller needle into the reservoir dome only. The angle between the needle and the scalp should be 25° or less to avoid needle contact with—and damage to—the diaphragm and seat at the base of the reservoir. (Figure 1.) If the valve is in an Anti-Siphon Model, never inject into the Anti-Siphon Device.

Upon removal of the needle from the reservoir dome, pump the chamber several times to flush the fluids into the distal catheter. (Figure 2.)

Flushing and Shunt-Patency Check

To check the patency of, or express fluid into the distal catheter, pump the reservoir dome several times using transcutaneous finger pressure. (Figure 2.)

Note: The valve diaphragm prevents flushing into the proximal (ventricular)
Infant, increased scalp tension at the deterioration of consciousness. In the irritability, listlessness, drowsiness, characterized by headache, vomiting, increasing intracranial pressure due to shunt failure. These signs and symptoms must be kept under close observation for signs and symptoms of increasing intracranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, nuchal rigidity, and other signs of deterioration of consciousness. In the infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins will be noted.

This device is made of silicone rubber, which like most rubber, may stick to itself when dry. This tendency to stick may result in slight valve performance variations which may differ from label specifications. When wet, the silicone rubber should not stick, therefore, the surgeon must verify that the valve components are wet and that fluid flows freely through the valve.

This product has not been tested for drug compatibility and therefore is not intended for drug administration.

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

Silicone tubing may be easily cut or torn when instruments are used to secure it to a connector. The use of instruments to attach silicone catheters to connectors should be avoided. When instruments are used, carefully inspect the tubing for nicks or other damage prior to closure.

Precautions

Prior to surgery, prospective patients or their representatives should be informed of the possible complications associated with the use of this product.

Integra NeuroSciences recommends the use of a low-pressure distal catheter (closing pressure 54mm H2O or less) with all pressure ranges of the Pudenz Flushing Valve, in order to allow the valve diaphragm (and the Anti-Siphon, if appropriate) to control shunt pressure.

If the physician requires that a medium or high pressure (slit valve) distal catheter is needed, we recommend THESE ONLY be used with the low pressure Pudenz Flushing Valves (Catalog Numbers NL550-1330, NL540-1351, NL540-1410, and NL540-1411).

The catheters used with this device should be carefully secured to the connectors in such a manner as to avoid cutting or occluding the tubing.

Fluid flow through the flushing valve should be verified immediately prior to implantation. (See Instructions for Use.) Flush the valve with gentle syringe pressure. Pressure created by excessive syringe flushing may temporarily deform the silicone elastomer valve diaphragm, which will cause abnormally low pressure-test results.

Never inject into the anti-siphon device! Any penetration of the anti-siphon diaphragm will jeopardize its fitness for use.

If a hypodermic injection into the flushing valve is required, use a 25-gauge or smaller needle and inject through the reservoir dome only.

Injections at an angle greater than 25° from the scalp may puncture the diaphragm seat, which could allow a backward flow of CSF into the brain and loss of the pressure-control function.

Complications

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as the patient’s response, reaction or degree of intolerance to any foreign object implanted in the body.

The principal complications associated with cerebrospinal fluid shunting into the right atrium or peritoneum are shunt obstruction, functional failure of the shunt system, infection or intracranial hypotension.

Shunt obstruction may occur in either the proximal ventricular catheter or in the distal, atrial or peritoneal catheters. Ventricular catheters may be obstructed by particulate matter such as blood clots, fibrin or brain fragments. If not properly located in the lateral ventricle the catheter may become embedded in the ventricular wall or choroid plexus. Less commonly, the catheter may be obstructed by excessive reduction of ventricular size to slit-like proportions.

Cardiac and peritoneal catheters may also be obstructed by particulate matter. The intra-atrial segment of the cardiac catheter may be obstructed by investment in a thrombus. Emboli from...
the latter may seed the pulmonary circulation sufficiently to result in pulmonary artery hypertension and cor pulmonale. Penumetal catheters may be obstructed by the omentum or coiled loops of bowel.

Loss of valve and/or reservoir patency may result from obstruction of the fluid pathway by particulate matter such as blood clots or other biological accumulations.

Functional failure of the shunt system due to separation of its component parts can result in serious complications. Ventricular catheters may migrate into the lateral ventricles. Should the cardiac catheter become detached, it may lodge in the right atrium or ventricle or, rarely, in the pulmonary artery. Peritoneal catheters may migrate completely into the peritoneal cavity. Volvulus and perforation of intra-abdominal viscera may occur or the catheter may be extruded.

Infection is a common and serious complication of a shunting system and is most frequently caused by skin contaminants. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection. The presence of a foreign body (i.e. the shunting system) may trigger ventriculitis or a dormant meningitis. Intracranial infection may then be disseminated throughout the body via the distal catheter. Lesions developing from the breakdown of skin or tissue over the shunting system may also serve as foci of serious infections. In the event of an infection, removal of the shunt is indicated in addition to the appropriate therapy.

Excessive lowering of intracranial pressure may result in complications, particularly in the infant. These include subdural hematoma, markedly sunken fontanels, overriding of cranial bones and the conversion of a communicating to a noncommunicating hydrocephalus due to obstruction of the aqueduct of Sylvius.

Failure of the shunting system may be evidenced by any or all of the following: continuing symptoms of increased intracranial pressure, the subcutaneous exudation of CSF along the pathway of the shunt and leakage of fluid through the surgical wound. These failures require immediate replacement of the shunting system or of the affected component.

### Product Information Disclosure
Integra NeuroSciences has exercised reasonable care in the choice of materials and manufacture of this product. Integra NeuroSciences excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness. Integra NeuroSciences shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Integra NeuroSciences neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

### Product Order Information
All products can be ordered through your Integra NeuroSciences Neuro Specialist or customer service representative or by contacting:

Integra NeuroSciences
311 Enterprise Drive
Plainabor, NJ 08536 USA
Telephone: 1-800-654-2873
Outside the US: 719-275-0500
Fax: 719-275-5383

or

Integra NeuroSciences
Newbury Road, Andover
Hampshire SP10 4DR England
Tel: +44(0) 1264-332-113
Fax: +44 (0) 1264-332-113

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician. Do not use if the package has been opened or damaged.

### Symbols Used On Labeling
- See instructions for use
- Expiration date
- Do not reuse after opening
- Lot number
- Sterile unless package is opened or damaged.

**Method of sterilization:** Ethylene oxide. Product complies with requirements of directive 93/42/EEC for medical devices.

### Bibliography


### Dimensional Illustrations (All dimensions are nominal)

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<tr>
<th>Catalog Number</th>
<th>Burr Hole Size (mm)</th>
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<td>16</td>
<td>Pudenz Flushing Valve, with integral connectors, Low Pressure</td>
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<td>Pudenz Flushing Valve, with integral connectors, Medium Pressure</td>
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**Pudenz Flushing Valve with integral connectors, 12mm and 16mm**

**Pudenz Flushing Valve with Anti-Siphon Device, 12mm and 16mm**